UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/958,991	10/23/97	KORENBERG J	P-UE-2817

EXAMINER

TUNG, M

ART UNIT	PAPER NUMBER
1644	18

DATE MAILED: 05/06/99

HM22/0508

LAURA A CORUZZI ESQ.
PENNIE & EDMONDS LLP
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

2 - Mail Copy

Office Action Summary	Application No. 08/956,991	Applicant(s) Korenberg
	Examiner Mary B. Tung	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Feb 16, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 11, 13-19, 21-29, and 31-49* is/are pending in the applicat

Of the above, claim(s) *11, 13-19, and 21-29* is/are withdrawn from consideration

☒ Claim(s) *44-46* is/are allowed.

☒ Claim(s) *1, 31-43, and 47-49* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-30 were originally elected.

Claims 2-10, 12, 20 and 30 were cancelled in the paper filed 2/16/00, Paper No. 17.

Claims 31-49 were added in Paper No. 17.

Claims 11, 13-19 and 21-29 stand withdrawn as being drawn to a non-elected invention.

Claims 1 and 31-49 are under consideration.

Specification

1. The Applicants did not comply with the Examiner's request to capitalize trademarks noted in the application because the Applicants argue that "BIONICK," page 48, line 16, "PHOTOMETRIC COOLED-CCD," page 48, line 35 and bridging over to page 49, line 1, "NYBOND," page 49, line 5, "RADPRIME," page 49, line 7, and so on, used in the specification are not registered trademarks. However, "HYBOND" is a registered trademark of Amersham. "Nybond" is believed to be a typographical error, as discussed below. BioNick is a registered trademark of Life Technologies, and so forth. The tradenames should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. Each letter of the trademarks must be capitalized. *See MPEP 608.01(V)* and *Appendix 1.*

3. The disclosure stands objected to because of the following minor informality: There appears to be an extra parentheses, ')' on page 10, line 10. Additionally, "NYBOND" on page 49, line 5, appears to be a misprint and should read as "HYBOND". Appropriate action is required.

Claim Rejections - 35 U.S.C. § 101 and Claim Rejections - 35 U.S.C. § 112

4. *35 U.S.C. § 101* reads as follows:
"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

6. The rejection of claim 1 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility is hereby withdrawn in light of the disclosure on page 43 that maps the DS-CAM nucleic acid to a region of the chomosome linked to Downs Syndrome.

Claim Rejections - 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of *35 U.S.C. § 102* that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Applicant's arguments filed in Paper No. 17 have been fully considered but they are not persuasive.

9. Claim 1 stands rejected under 35 U.S.C. 102(a) as being anticipated by Korenberg, et al. *(PNAS USA, 91;4997-5001, 1994),* for the same reasons set forth in the action mailed 8/16/99, Paper No. 15.

10. The Applicants argue using various cited case law references, that Korenberg, et al. does not teach each and every element of the claimed invention. However, this is not found persuasive because an inherent property of product taught in the art provides proper anticipation. *see Ex parte Noviski 26 USPQ2d 1389.* Therefore, the reference teachings anticipate the claimed invention.

11. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Genexpress cDNA Program *(GenBank, Accession # F13426),* is hereby withdrawn in light of the amendment to claim 1 in Paper No. 17, which now recites a nucleic acid which encodes a polypeptide comprising SEQ ID NO: 1.

12. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Genexpress cDNA Program *(GenBank, Accession # Z41519),* is hereby withdrawn in light of the amendment is Paper No. 17 to Claim 1.

Claim Rejections - 35 U.S.C. § 103

13. The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Genexpress cDNA Program *(GenBank, Accession # F13426)* or Genexpress cDNA Program *(GenBank, Accession # Z41519)* in view of Gallatin, et al., (US Patent No. 5,525,487) is hereby withdrawn as discussed under 35 U.S.C. 102, *supra*.

The following new grounds for rejection are necessitated by amentment:

Claim Rejections - 35 U.S.C. § 102

14. The following is a quotation of the appropriate paragraphs of *35 U.S.C. § 102* that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 33-35, 38 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Korenberg, et al. *(PNAS USA, 91;4997-5001, 1994)*.

16. Korenberg, et al. teach an isolated nucleic acid obtained from patients with Down Syndrome (see the abstract and page 4997, col. 1, last paragraph and bridging over to page 4998, col. 1). DS-CAM would inherently be encoded by nucleic acid taught by Korenberg, et al, absent evidence to the contrary. The isolated chromosomal DNA isolated for Southern blot analysis, as taught on page 4998 would also be expected to hybridize to SEQ ID NO: 1 under the recited conditions, absent evidence to the contrary. Claims 33 and 35 are included because of the high homology among the sequences idenfied as SEQ ID NOS: 1, 7, 8, 9 and 10, which encodes SEQ ID NO: 11, as recited in claim 33, one would expect hybridization of said sequences under the claimed conditions, absent evidence to the contrary.

17. The Applicants argue using various cited case law references, that Korenberg, et al. does not teach each and every element of the claimed invention. However, this is not found persuasive because an inherent property of product taught in the art provides proper anticipation. *see Ex parte Noviski 26 USPQ2d 1389*. Therefore, the reference teachings anticipate the claimed invention.

18. Claims 33-37, 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Genexpress cDNA Program *(GenBank, Accession # F13426)*.

19. The F13426 sequence listing teaches a 309 bp fragment of nucleic acid which encodes a 103 amino acid fragment of SEQ ID NO: 2. The F13426 sequence listing teaches that the sequence fragment has a 95.1% identity with the nucleic acid sequence that encodes SEQ ID NO:2. The F13426 sequence listing also teaches the cDNA, as recited in claim 47 was cloned into a *lafmid BA* vector and a mRNA sequence, as recited in claim 48. Claims 36 and 37 are included because the *lafmid BA* vector was derived from the pEMBL vector, which is an *E. coli* to yeast shuttle plasmid vector and thus requires a host (recombinant) cell for storage and shipment as evidenced by ATCC Catalog No. 37395. Claims 33 and 35 are included because of the high homology among the sequences idenfied as SEQ ID NOS: 1, 7, 8, 9 and 10, which encodes SEQ ID NO: 11, as recited in claim 33, one would expect hybridization of said sequences under the claimed conditions, absent evidence to the contrary.

20. The Applicants argue using various cited case law references, that # F13426, et al. does not teach each and every element of the claimed invention. However, this is not found persuasive because an inherent property of product taught in the art provides proper anticipation. *see Ex parte Noviski 26 USPQ2d 1389*. Therefore, the reference teachings anticipate the claimed invention.

Claim Rejections - 35 U.S.C. § 103

21. The following is a quotation of *35 U.S.C. § 103* which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under *subsection (f) or (g)* of *section 102* of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

22. Claims 1, 31-43 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenberg, et al. *(PNAS USA, 91;4997-5001, 1994),* in view of Gallatin, et al., (US Patent No. 5,525,487).

23. Korenberg has been discussed, *supra.* Korenberg does not teach or a method for expression of a DS-CAM related protein. However, the '487 patent teaches that in order to produce the polypeptide in large quantities, host cells transfected with a vector

comprising a nucleic acid, can be used in a method of expressing the polypeptide then isolating the polypeptide from the cell culture medium, as recited in claim 49, (see col. 3, lines 12-17). One of ordinary skill in the art at the time the invention was made would have been motivated to use the DNA taught by Korenberg in a method for expression of a DS-CAM related protein, in order to produce large quantities of the protein as taught in col. 3. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

24. The Applicants argue using various cited case law references, that Korenberg, et al. does not teach each and every element of the claimed invention. However, this is not found persuasive because an inherent property of product taught in the art provides proper anticipation. *see Ex parte Noviski 26 USPQ2d 1389.* Therefore, the reference teachings anticipate the claimed invention.

25. Claims 33-37 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genexpress cDNA Program *(GenBank, Accession # F13426),* in view of Gallatin, et al., (US Patent No. 5,525,487).

26. # F13426 has been discussed, *supra.* # F13426 does not teach or a method for expression of a DS-CAM related protein. However, the '487 patent teaches that in order to produce the polypeptide in large quantities, the host cells, can be used in a method of expressing the polypeptide then isolating the polypeptide from the cell culture medium, as recited in claim 49, (see col. 3, lines 12-17). One of ordinary skill in the art at the time the invention was made would have been motivated to use the DNA taught by # F13426 in a method for expression of a DS-CAM related protein, in order to produce large quantities of the protein as taught in col. 3. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

27. The Applicants argue using various cited case law references, that # F13426, et al. does not teach each and every element of the claimed invention. However, this is not found persuasive because an inherent property of product taught in the art provides proper anticipation. *see Ex parte Noviski 26 USPQ2d 1389.* Therefore, the reference teachings anticipate the claimed invention.

Allowable Subject Matter

28. Claims 44-46 are allowed. The prior art does not teach a nucleic acid sequence set forth in SEQ ID NOS: 5-8 or 10, which encodes SEQ ID NO: 11, 15 nucleotides or longer.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

30. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

32. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

May 5, 2000
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

Your query was:
pembl

ATCC Number: 37395 Designations: pEMBL9 Sites: Poly

ATCC Number: 37395
Designations: pEMBL9
Sites:
Polylinker sites: EcoRI SmaI BamHI SalI AvaI PstI HindIIICloning
sites: EcoRI SmaI BamHI SalI AvaI PstI HindIII
Size (kb): 3.990
Vector type: plasmid
Features:
marker(s): ampR
insert detection: lacZ'
Depositors: G. Cesareni
Applications:
vector permitting construction of fusion proteins
vector permitting production of single-stranded DNA
ssDNA-producing plasmid with polylinker in lacZ'.
References:
RF2018: Dente L et al. pEMBL: a new family of single stranded plasmids. Nucleic Acids Res. 11: 1645-1655, 1983 PubMed: 83168912
RF2019: Baldari C and Cesareni G. Plasmids pEMBLY:new single-stranded shuttle vectors for the recovery and analysis of yeast DNA sequences. Gene 35: 27-32, 1985 PubMed: 85286354
Propagation:
ATCC medium: 1227 LB Medium (ATCC medium 1065) with 50 mcg/ml ampicillin
Temperature: 37C
Shipped: freeze-dried Escherichia coli 71/18
Price Code: B
Biosafety Level: 1
Revised: Feb 27, 1998

This page was generated by SFgate 5.111.